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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/973,956 | 10/11/2001 | Ronald W. Mink | 090793-05210 | 7403 |
| 22204 | 7590 | 04/27/2005 | EXAMINER | |
| NIXON PEABODY, LLP 401 9TH STREET, NW SUITE 900 WASHINGTON, DC 20004-2128 | | | SORKIN, DAVID L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1723 | |

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/973,956 | MINK ET AL. | |
| | Examiner | Art Unit | |
| | David L. Sorkin | 1723 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 April 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 50-56 and 58-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 54-56, 63 and 65 is/are allowed.

6) Claim(s) 50-53, 58-62, 64 and 66 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>08 April 2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission (IDS) filed on 08 April 2005 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 50-53, 58, 59, 64 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Kremer (US 4,635,488). Regarding claim 50, Kremer ('488) discloses a device for collecting and assay of fluids comprising a housing (11) having a fluid receiving end (14) and an assay portion; a lateral flow assay strip (44) contained substantially within the assay portion, the assay strip containing at least one reagent that is used to detect the presence or absence of at least one analyte in a fluid (see col. 8, lines 51-66); a collection strip (12a) for transporting the fluid from a fluid source to the assay strip, the collection strip including, a first narrow end contained within the housing an in fluid communication with the assay strip and a second enlarged end (28a) protruding from the fluid receiving end; and a blocking strip (52) coupled between and in flow communication with the lateral flow assay strip and the collection strip. Regarding

claim 51, the collection strip comprises a capillary matrix adapted for rapid wicking of fluid from a fluid source to the assay strip (see col. 5, lines 31-43; col. 7, lines 7-8).

Regarding claim 52, while the reference explicitly discloses the fluid source being an oral cavity (see col. 6, lines 62-64), “the manner or method in which such a machine is to be utilized is not germane to the issue of patentability of the machine itself” *In re Casey*, 152 USPQ 235 (CCPA 1967). Regarding claim 53, the second end is one of a paddle-shape and a bulbous shape (see Fig. 3). Regarding claim 58, the assay strip is an immunochromatography strip (see col. 8, lines 57-58). Regarding claim 59, a sample adequacy indicator is disclosed (see col. 8, lines 23-27). Regarding claim 64, the blocking strip contains at least one blocking agent (See col. 10, lines 28-29).

Regarding claim 66, the collection strip is adsorbent (see col. 5, lines 11-51).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer (US 4,635,488), as discussed above with regard to claim 50, in view of Ullman (US 4,624,929). Kremer ('488) does not detail the chemistry of the assay. Ullman teaches assay components including an immunospecific binding partner with a detectable label, enzyme labeled binding partners antigens and antibodies (see col. 8, lines 8-14; col. 9 line 68 and col. 12 lines 44-46). It is considered that it would have

been obvious to one of ordinary skill in the art to have used the assay chemistry of Ullman ('929) in the device of Kremer ('488), because the invention of Kremer ('488) concerns the structure of the device and one would look to the prior art for the chemical aspects of the assay, especially to Ullman ('929) because both Ullman ('929) (see col. 7 line 16) and Kremer ('488) concern testing saliva.

Allowable Subject Matter

6. Claims 54-56, 63 and 65 are allowed.

Conclusion

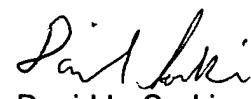
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 571-272-1148. The examiner can normally be reached on 9:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David L. Sorkin
Primary Examiner
Art Unit 1723

DLS